



ADVANCING SCIENCE, SERVING SOCIETY

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To: Jerry Moore
NIH Regulations Officer
Office of Management Assessment
National Institutes of Health
6011 Executive Blvd., Suite 601, MSC 7669
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Dear Mr. Moore,

The American Association for the Advancement of Science (AAAS) appreciates the opportunity to comment on the Proposed Rule on the "Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding is Sought and Responsible Prospective Contractors," published in the *Federal Register* on May 21, 2010.

We are very pleased that several of the recommendations that AAAS and other groups made in response to the Advance Notice of Proposed Rulemaking (ANPRM) pertaining to objectivity in research have been incorporated into the current proposal. These suggestions included training requirements for investigators, the inclusion of subgrantees, the removal of the exemption from disclosing non-profit income, and management plans in which the specifics would fall to the institution's discretion.

Before we address specific elements within the Proposed Rule, we would like to address a broader challenge that recent events have raised: specifically, when a research institution imposes sanctions for conflict of interest violations, and the guilty researcher leaves that institution for another, thereby avoiding the original sanctions. This seems contrary to the principles and intent that underlie the proposed rulemaking. While an increased role for institutions, as reflected in the new proposal, is warranted, individual researchers must be held accountable for their behavior and the public must be assured that this will indeed be the case. We strongly recommend that the proposed rules follow the PHS model governing research misconduct, where individuals and institutions found to have violated existing regulations are both held accountable and the sanctions applied to individuals stay in force no matter where the individual does his/her research.

With respect to specific elements within the Proposed Rule, AAAS has some concerns, recommendations, and questions for clarification. Our primary concerns center on "significant financial interest," travel reimbursement, and institutional responsibilities.

- **Definition of Significant Financial Interest.** The definition of "significant financial interest" (F.R., page 28705) potentially includes equity interests that are not necessarily directed or controlled by the investor—for example, a retirement account. It would be difficult to parse out an investigator's financial interest with regard to those types of

investments. We therefore recommend a carve-out for non-controlled group investment vehicles.

- **Travel - Benefit v. Reimbursement** (F.R., page 28692). This provision is too easily circumvented. What is really important is to understand the benefit individuals may have received that could bear on their research. Travel reimbursement is one type of benefit—but by limiting this part of the disclosure to reimbursement, investigators would not be required to disclose payments for travel that were routed through their employer, nor would they be required to disclose benefits received that were directly paid by a third party. NIH should clarify this terminology to ensure that the relevant information sought would actually be disclosed.

- **Institutional Responsibilities** (F.R., page 28705, Section 50.603). The disclosures are required for payment/compensation that (under Section 50.603, definition of significant financial interest) “reasonably appears to be related to the Investigator’s institutional responsibilities.” Earlier in that section, institutional responsibilities are defined as an Investigator’s “professional responsibilities on behalf of the Institution....”

How is this definition applied to investigators, for example, who serve on boards not on behalf of an institution, but based on the investigator’s own credentials, for which the investigator is compensated? Is that related to the individual’s responsibilities on behalf of the institution? “On behalf of” should be more clearly defined.

- **Institutional Responsibilities** (F.R., page 28705, Section 50.603). If an award would change an individual’s institutional responsibilities, it would seem the disclosure should be made based on the anticipated institutional responsibilities if the funding applied or is awarded, not current responsibilities; this is not clear.
- **Definition of Research** (F.R., page 28705, Section 50.603). The definition of “research” includes “basic and applied research and product development.” We are uncertain as to the scope of the term “product.” Listing examples of what would constitute a “product” under the proposed rule (e.g., a diagnostic test, a drug, a published article, book or book chapter) would add clarity to a core definition within the proposed rule.

Furthermore, AAAS is concerned that the proposed changes to the definition of “research” could risk creating an environment where institutions broadly apply their own interpretation in order to minimize the risk of noncompliance. One possible resolution of this would be for PHS to include the regulation in specific Request for Proposals or funding instruments (e.g., contracts) in order to be clear about when the provision applies. This could be especially beneficial given the broader definition of funding mechanisms (e.g., program project) and other applicable statutes. However, we also recognize that this places an additional burden on NIH contracting officers to determine accurately when the conflict of interest regulations should be applied. In order to ensure a smooth transition, PHS will likely need to augment its staffing and training capabilities so that the requirement is applied appropriately and fairly. PHS should assure the research community that it will have the required personnel, funding, and training to implement the regulations in a timely and effective manner.

- **Payments from Non-profits** (F.R., page 28693). While requiring disclosure of payments from non-profits makes good sense, we are not persuaded that the Proposed

Rule would achieve the intended purpose (see F.R., page 28693), at least not without placing an undue burden on institutions. This is so because in order to truly identify a financial conflict of interest, institutions would need to consider the non-profit's source of funding. It is not clear how this could reasonably be done. Would a non-profit institution be able, given complexities of funding for many non-profits, to disclose such information? In instances where funding from multiple sources is commingled, can it be expected that the non-profit could attribute the disclosed payment to any particular funder? We strongly recommend that the implementation of this requirement be carefully designed to maximize undue burdens on institutions applying for or receiving PHS funding.

- **Timing for Disclosures** (F.R, page 28705, Section 50.603, Significant financial interest, sub-section (1)(i) and (ii)). Under the first two sub-sections of the definition that addresses the disclosure requirement for publicly traded or non-public entity, when a significant financial interest (SFI) exists the value of any remuneration received from the entity in the twelve months preceding must be disclosed. When to begin calculating the 12-month period for disclosure is not clear: possibilities include the time of proposal submission, the time of award, or the effective date of the award. This timing issue should be clarified. Finally, the third part of the SFI, relating to intellectual property rights, has no timeframe for disclosure.
- **Management and Reporting** (F.R. page 28707). Section 50.605(a)(5)(i) describes the three criteria that, if met, would require public disclosure. Section 50.605(a)(5)(i)(A) describes the first criterion – a significant financial interest that is still held by the investigator. Because a payment or reimbursement would not be considered “still held” it is unclear how this criterion applies to those types of disclosures.
- **Inconsistency in Proposed Rule.** In several places of the proposal, mention is made of the need to ensure that “the design, conduct, *and* reporting of the research” (emphasis added) are protected against bias from an investigator's financial conflict of interest (F.R, pages 28707, 28708). However, on page 28705, the definition of “manage” uses the conjunction “or,” as in “the design, conduct *or* reporting of research,” (emphasis added) rather than “and.” The use of “or” in such cases as well as its inconsistent use in the document confuses rather than clarifies. We recommend that “and” be used throughout the document in similar contexts.

We hope these suggestions will assist the PHS in finalizing its policies. AAAS is the world's largest multidisciplinary science society, representing the interests of ten million scientists worldwide, and publisher of the prestigious peer-reviewed journal *Science*. We have a long-standing interest and expertise in conflicts of interest in scientific research. We stand ready to work with the PHS in addressing this important and complex subject.

Sincerely,



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